

**REMARKS**

Claims 1-24 are currently pending.

The withdrawal of the prior rejection of U.S. Patent no. 3,951,945 (Heeson et al.) is hereby acknowledged with appreciation.

**Allowable Subject Matter**

The Examiner's indication that claims 16 and 19-24 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims is hereby acknowledged with appreciation.

**Summary of the Telephone Interview**

Applicant's representative, Kevin J. Dunleavy, conducted a telephonic interview with Examiner Carr on April 28, 2006. During the telephonic interview, the sole outstanding rejection was discussed as it pertains to claim 1. No agreement was reached during the telephonic interview. The arguments presented during the telephonic interview are reproduced in detail below.

**The Sole Outstanding Rejection**

Claims 1-15 and 17-18 have been rejected under 35 U.S.C. §102(b) as being clearly anticipated by U.S. Patent no. 5,458,910 (Greutzmacher et al.). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

The present invention relates to a process for preparing a mixture of sorbitol fatty acid esters and sorbitol anhydride fatty acid esters. The process includes the step of reacting a reaction mixture which is essentially free from water, comprising sorbitol and at least one free fatty acid. The molar ratio of free fatty acid to sorbitol is at least 7:1. The reaction is carried out at a temperature and for a time sufficient to effect an average degree of sorbitol hydroxyl substitution of from about 3 to about 5.5 fatty acid groups per sorbitol molecule. The reaction product is a mixture including sorbitol fatty acid esters and sorbitol anhydride fatty acid esters.

The Examiner, in her rejection, relies on col. 6, lines 1-8 of Greutzmacher et al. Col. 6, lines 1-8 of Greutzmacher et al. teaches that the sorbitol fatty acid tetraester can be prepared by a variety of methods well known by those skilled in the art including the acylation of

sorbitol with a free fatty acid or a mixture of free fatty acids. Thus, as the Examiner correctly points out, Greutzmacher et al. mentions that the sorbitol fatty acid esters of Greutzmacher et al. can be made by acylation of sorbitol with a free fatty acid. However, Greutzmacher et al. provides no further details on the process which employs a free fatty acid. As a result, Greutzmacher et al. does not teach or suggest the use of a molar ratio of free fatty acid to sorbitol of at least 7:1, as required by claim 1 of the present application.

The Examiner apparently takes the position that it would be inherent in the use of the prior art free fatty acid process mentioned in Greutzmacher et al., that a skilled person would use a ratio of free fatty acid to sorbitol of at least 7:1 based on the desire to obtain a degree of substitution in the sorbitol fatty acid esters of 3.6 to 4.4 (col. 5, lines 32-34 of Greutzmacher et al.) and the ratios of fatty acid esters to sorbitol used in the examples of Greutzmacher et al. However, the applicant does not agree with this conclusion for the reasons set forth below.

First, it should be noted that the molar ratio of fatty acid ester to sorbitol of Example 1 of Greutzmacher et al. is about 8:1, and not 13:1 as the Examiner suggests. Specifically, the methyl oleate of Example 1 of Greutzmacher et al. has a molecular weight of 296.49, which results in about 0.08 moles of methyl oleate, based on use of 23.75 grams. 1.82 grams of sorbitol provides about 0.01 moles of sorbitol since the molecular weight of sorbitol is 182.17. This results in a molar ratio of about  $0.08/0.01 = \text{about } 8.0$ .

More important, though, is the fact that Example 1 of Greutzmacher et al. is a totally different process from the process claimed in the present application since Example 1 of Greutzmacher et al. employs a fatty acid ester as a reactant, rather than a free fatty acid.

The only mention in Greutzmacher et al. of a process employing a free fatty acid, as claimed in the present claims, is found at col. 6, lines 1-8 of Greutzmacher et al. In this context, Greutmacher et al. refers to the process employing the free fatty acid as being a method well known by those skilled in the art. See col. 6, line 2 of Greutzmacher et al. From this, it is clear that the sole reference in Greutzmacher et al. to a process employing a free fatty acid is a reference to a prior art process. As a result, a skilled person reading Greutzmacher et al. and desiring to employ a process involving a free fatty acid, as claimed in the present application, would consult the prior art for the molar ratio of reactants to be used in such process and would not look elsewhere in Greutzmacher et al. for this information. This is confirmed by the fact that Greutzmacher et al. only gives details and examples of processes

employing a fatty acid ester, and not a process employing a free fatty acid. See e.g. col. 6, lines 23-32 and the Examples of Greutzmacher et al.

The Examiner appears to suggest that a skilled person, rather than consulting the prior art for the molar ratio of reactants to employ in the free fatty acid process, would extrapolate the molar ratio of reactants for the free fatty acid process from the molar ratios employed in the Examples of Greutzmacher et al. for the different, fatty acid ester process. However, the applicant disagrees with this suggestion for the following reasons.

First, if the skilled person extrapolated a molar ratio of free fatty acid to sorbitol of at least 7:1 from the examples of Greutzmacher et al., as suggested by the Examiner, then the skilled person would not be employing the free fatty acid method that Greutzmacher et al. mentions at col. 6, lines 1-8. This can be seen from U.S. Patent no. 3,951,945 (Heeson et al.), which provides details of the closest prior art method to the present invention that employs a free fatty acid, as mentioned in Greutzmacher et al. As discussed in the applicant's previous response, Heeson et al. teaches that the molar ratio of polyalcohol to fatty acid is between 4:1 and 1:5. See e.g. col. 3, lines 33-40 and claim 8 of Heeson et al. Thus, the highest ratio of free fatty acid to sorbitol disclosed by Heeson et al. is 5:1.<sup>1</sup> Accordingly, if a skilled person were to extrapolate the ratio of free fatty acid to sorbitol as suggested by the Examiner, the skilled person would actually go against the teachings of the prior art, as represented by Heeson et al., regarding the proper molar ratio of free fatty acid to sorbitol to apply in the free fatty acid process.

In this regard, it is also highly relevant that:

- (1) Greutzmacher et al. only refers to the process employing free fatty acid as a prior art process and does not teach specific details of the free fatty acid process,
- (2) Heeson et al. describes the closest prior art process employing free fatty acid, and
- (3) the Examiner withdrew the previous rejection of the claims over Heeson et al. in view of applicant's arguments based on the teachings of Heeson et al. in the prior response.

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<sup>1</sup> Heeson et al. gives the inverse molar ratio of that claimed in the present claims, i.e. the molar ratio of sorbitol to free fatty acid. Thus, a molar ratio of 1:5 in the terms used in Heeson et al. corresponds to a molar ratio of 5:1 in the terms employed in the present claims.

A second reason that a skilled person would not extrapolate the claimed molar ratio of free fatty acid to sorbitol from the examples of Greutzmacher et al. as the Examiner suggests, is that Greutzmacher et al. warns a skilled person that different methods of producing sorbitol fatty acid esters give different results. Specifically, at col. 6, lines 9-11 of Greutzmacher et al. it is stated that,

“Depending on the method by which the sorbitol fatty acid ester is made, it contains varying proportions of esterified sorbitol anhydrides.”

This is important to the skilled person since Heeson et al. teaches that,

“During the reaction [of sorbitol with free fatty acids] a very considerable amount of the sorbitol (i.e. more than 75%) is converted into anhydrocompounds.... Due to the formation of these anhydrocompounds the products become less hydrophilic (hydroxyl groups are eliminated) and their application in foodstuffs encounters difficulties as the ethers in the body are not metabolized in the way that is normal with polyalcohols.”

See col. 1, lines 5-17 of Heeson et al. Thus, from Heeson et al. and Greutzmacher et al., the skilled person is informed as follows:

- (1) the formation of anhydrocompounds (sorbitol anhydrides) causes difficulties in the application of the sorbitol esters in foodstuffs (Heeson et al. col. 1, lines 12-17),
- (2) different methods of making the sorbitol esters result in different proportions of sorbitol anhydrides (anhydrocompounds) (Greutzmacher et al. col. 6, lines 9-11), and
- (3) the reaction of sorbitol with free fatty acids produces a very considerable amount of anhydrocompounds (sorbitol anhydrides) (Heeson et al. col. 1, lines 5-12).

Thus, a skilled person would be led away from varying the molar ratio of free fatty acids to sorbitol outside the range of 1:4 to 5:1 disclosed in Heeson et al., based on the examples of Greutzmacher et al. since Greutzmacher et al. desires to use its products in foodstuffs. See e.g. col. 1, line 11; col. 4, lines 24-28 and col. 4, lines 44-51 of Greutzmacher et al. The reason for this is that Heeson et al. teaches that anhydrocompounds can present difficulties for use in foodstuffs and because Heeson et al. also teaches that the reaction involving free fatty acid produces a very considerable amount of anhydrocompounds.

In fact, Heeson et al. points out that,

"It is surprising that the stability of e.g. the sorbitol fatty acid esters is so high that, in the reaction with free organic acids or with anhydrides thereof, a relatively small amount amount of sorbitol anhydrocompounds is formed."

See col. 2, lines 58-62 of Heeson et al.

Moreover, the examples of Heeson et al. support the expectation that higher ratios of free fatty acids to sorbitol produce greater quantities of the undesirable anhydrocompounds. More specifically, Examples XIII-XV of Heeson et al., are provided to show the effect of varying the molar ratio of free fatty acid to sorbitol. See col. 9, lines 21-25 of Heeson et al. Example XIII, which employs a molar ratio of free fatty acid to sorbitol of 5:1<sup>2</sup>, produces 18.1% of undesirable anhydrocompounds, whereas examples XIV and XV, which employ lower molar ratios of free fatty acid to sorbitol of 1.0 and 0.33, respectively, produced only 3.9-5.5% of the undesirable anhydrocompounds. Accordingly, Examples XIII-XV of Heeson et al. support an expectation that the use of a high molar ratios of free fatty acids to sorbitol would result in significantly higher production of undesirable anhydrocompounds. This would lead a skilled person to the conclusion that molar ratios in excess of 7:1, as claimed in the present claims, should be avoided due to the expectation that large amounts of undesirable anhydrocompounds would be produced at such molar ratios.

Finally, the Examiner's conclusion that a skilled person would extrapolate the molar ratio to be used in the free fatty acid process is based, in part, on the mention at col. 5, lines 32-34 of Greutzmacher et al. that it is desirable to produce sorbitol fatty acid esters having a degree of substitution of from about 3.6 to about 4.4. At least two examples of Heeson et al., namely, Example XIII and Comparative Example a, appear to show the ability of the process of Heeson et al. to produce fatty acid esters having the desired degree of substitution of Greutzmacher et al., without exceeding the maximum molar ratio of free fatty acid to sorbitol of 5:1 disclosed in Heeson et al. Specifically, Example XIII of Heeson et al. employs a molar ratio of free fatty acid to sorbitol of 5:1 and produces 98% of tri- and higher sorbitol fatty acid esters, thereby demonstrating the apparent ability of the process of Heeson et al. to achieve the desired degree of substitution of Greutzmacher et al. Similarly, Comparative Example a of Heeson et al. provides 85% of tri- and higher sorbitol fatty acid esters using a molar ratio of

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<sup>2</sup> Examples XIII-XV of Heeson et al. give the inverse molar ratio of that claimed in the present claims, i.e. the molar ratio of sorbitol to free fatty acid. Thus, a molar ratio of 0.2 in the terms used in Heeson et al. (Example XIII) corresponds to a molar ratio of 5:1 in the terms employed in the present claims.

free fatty acids to sorbitol of only 1:1. From these examples of Heeson et al., it would be apparent to a skilled person that the degree of substitution desired by Greutzmacher et al. could be achieved using the range of molar ratios disclosed in Heeson et al., without producing a high amount of undesirable anhydrocompounds. Thus, the skilled person would choose not to increase the molar ratio disclosed in Heeson et al. to greater than 7:1, as the Examiner suggests since:

- (1) Heeson et al. demonstrates that there is no need to operate at such high molar ratios of free fatty acid to sorbitol in order to produce the desired sorbitol fatty acid esters having a degree of substitution of 3.6 to 4.4, and
- (2) Heeson et al. creates the expectation that use of molar ratios of free fatty acids to sorbitol in excess of 5:1 would produce larger amounts of undesirable anhydrocompounds.

Accordingly, for at least these reasons, claims 1-15 and 17-18 are novel over Greutzmacher et al. Favorable consideration and withdrawal of the rejection of claims 1-15 and 17-18 under 35 U.S.C. §102(b) is requested for at least this reason.

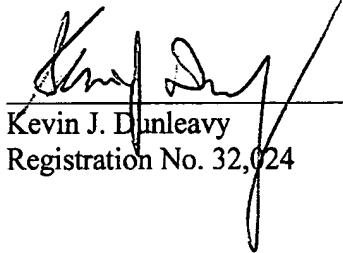
Claims 1-24 are also considered to be unobvious over Greutzmacher et al. for at least the same reasons, i.e. a skilled person would be led away from applying a molar ratio of free fatty acid to sorbitol of at least 7:1 by the combined teaching of Heeson et al. that the desired products can be obtained using lower molar ratios and the expectation from the examples of Heeson et al. that use of molar ratios of free fatty acids to sorbitol above 5:1 would lead to the production of larger amounts of undesirable anhydrocompounds.

Favorable consideration and issuance of a Notice of Allowance is requested.

The Commissioner is authorized to charge any additional fees associated with this response or credit any overpayment, to Deposit Account No. 50-0462.

Respectfully submitted,

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